Prediction of insomnia in sleep apnea

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Subtypes of COMISA can be distinguished based on the timing of appearance of insomnia symptoms. These subtypes can influence CPAP compliance in different ways.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24351

Bron
NTR

Verkorte titel
TBA

Aandoening

Insomnia, Obstructive Sleep Apnea

Ondersteuning

Primaire sponsor: Philips Electronics
Overige ondersteuning: HTSM/STW, Amphia Ziekenhuis, Philips Electronics, Eindhoven Engine.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Demographic parameters: age, gender, BMI

Polysomnography derived parameters:
* macrostructural sleep parameters

* number of apnea/hypopnea events per hour of sleep: apnea-hypopnea index (AHI)
* oxygen saturation

Sleep diary derived parameters:
* subjective macrostructural parameters
* night-to-night variability of sleep parameters
* estimators of misperception and other comparisons between object and subjective sleep data

Sleep disorders diagnosis: OSA, COMISA, insomnia, other

CPAP compliance (read out from CPAP device):
* number of hours the CPAP device has been used
* AHI

PPG and accelerometry derived parameters:
* macrostructural sleep parameters
* night-to-night variability of sleep parameters

Questionnaires:
* General questionnaire about main complaints
* Epworth Sleepiness Scale (ESS)
* Insomnia Severity Index (ISI)
* Hospital Anxiety and Depression Scale (HADS)
* Pittsburgh Sleep Quality Index (PSQI)
* Pre-Sleep Arousal Scale (PSAS)

Toelichting onderzoek

Achtergrond van het onderzoek

Currently, Continuous Positive Airway Pressure (CPAP) therapy is the treatment of choice for Obstructive Sleep Apnea (OSA), but a significant percentage of patients is or becomes non-compliant. It is hypothesized that insomnia may play a crucial role in CPAP adherence as OSA and insomnia frequently co-exist. This condition is referred to as comorbid insomnia and OSA: or called COMISA. However, it remains challenging to predict or diagnose COMISA, since insomnia complaints can appear minor compared to the OSA complaints, and insomnia can be masked by sleep fragmentation caused by obstructive events. Additionally, somnological expertise to diagnose insomnia in the presence of external sleep disruptors may be lacking. The diagnosis of insomnia relies on subjective assessments of sleep quality and complaints, while the diagnosis of OSA is based on a single-night polysomnography (PSG) measurement. However, long-term sleep measurements could play a pivotal role in obtaining more insight in a patient’s sleep pattern.
This prospective study will focus on phenotyping patients suspected of OSA, using PSG measurements and modern unobtrusive home-assessment techniques to evaluate both

objective and subjective sleep.

Doel van het onderzoek

Subtypes of COMISA can be distinguished based on the timing of appearance of insomnia symptoms. These subtypes can influence CPAP compliance in different ways.

Onderzoeksopzet

• Demographic parameters are known at the start of the study
• Polysomnography will be performed at the start of the study. Derived parameters will be obtained after the study using computational methods.
• Sleep diary data will be kept in an electronic sleep diary. Data will be obtained two weeks after the start of the study. In case of treatment with CPAP therapy, a secondary sleep diary data set will be obtained +/- 14 weeks after start of the study. Derived parameters will be obtained after the study using computational methods.
• Initial sleep disorders diagnosis will be obtained 2-3 weeks after the start of the study. Final sleep disorders diagnosis will be obtained +/- 14 weeks after the start of the study (as diagnosis can change during the study, based on conventional clinical care). Diagnosis is stated by the treating physician.
• CPAP compliance will be obtained +/- 12 weeks after start of the study. This is a read out of the CPAP device.
• PPG and accelerometry data will be obtained two weeks after the start of the study. In case of treatment with CPAP therapy, a PPG and accelerometry data set will be obtained +/- 14 weeks

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Planned for PSG
• Age older than 18
• Speaking and reading Dutch
• Be in possession of a computer with internet

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Known allergies for hard plastic (like in sport watches) or elastic band material
• Presence of wounds, injuries or infectious diseases on the skin where the wristband will be placed
• Tattoo on top of the wrist (where the sensor should be placed)
• Pregnancy
• Presence of autonomic dysfunction
• Having persistent heart rhythm disorders
• Conditions which will prevent taking part in questionnaires, for example due to language deficiency
• Inability to provide informed consent
• Inability to adhere to the study protocol due to severe neurologic or psychiatric disorders
• Using alpha-blocking or beta-blocking medication as these may affect heart rate, possibly resulting in unreliable measures of heart rate variability
• Currently displaying COVID-19 related symptoms, namely a fever, cough and/or difficulty breathing
• Having been positively tested as infected with COVID-19 in the past 14 days
• Travelled to or from high risk COVID-19 areas in the past 14 days
• Been in contact with a (suspected) COVID-infected person in the past 14 days

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2020
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8943
Ander register	METC MMC : W20.090

Resultaten